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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,424	10/10/2008	Chia-Ying Lin	2115-002753/US/NPB	3777

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EXAMINER	
BAHTA, KIDEST	
ART UNIT	PAPER NUMBER
2123	
MAIL DATE	DELIVERY MODE
09/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,424	LIN ET AL.	
	Examiner	Art Unit	
	KIDEST BAHTA	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/1/09, 6/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1.; Claims 1-20 are presented for examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollister et al. (Homgenization Sample procedure for calculating Trabecular Bone Effective Stiffness and tissue Level Stress)

Claims 1-20, Hollister discloses ,

1. A method of designing a biodegradable/bioresorbable tissue augmentation/reconstruction device, said method comprising: creating a material density distribution within a device design shape for discrete points during a material degradation lifecycle (Abstract) ;weighting said material density distribution using a weighting factor to determine a weighted density (Page 433, parg. 2); using said weight density to determine a material reinforcement of said device such that said device will retain predetermined structural properties during said material degradation lifecycle (Page 434, Methods).

2. The method according to claim 1 wherein said material density distribution is

creating using a technique chosen from the group consisting essentially of topology optimization, microstructure topology optimization, restricted topology optimization, image-based design, and computer-aided design techniques (Fig. 2).

3. The method of claim 2 wherein said topology optimization includes an algorithm employed to define said material density distribution at predetermined time points during said material degradation lifecycle (Page 436, Par. 2 and 3).

4. The method of claim 2 wherein said image-based design includes defining said material density distribution at predetermined time points during said material degradation lifecycle (Page 436, Par. 2 and 3).

5. The method of claim 2 wherein said general computer aided design techniques include defining said material density distribution at predetermined time points during said material degradation lifecycle(Page 436, Par. 2 and 3).

6. The method according to claim 1 wherein said weighting factor is chosen from the group consistently essentially of a linear weighting factor, a nonlinear weighting factor, a time past degradation factor, and a ratio of a degraded material property to initial material property (Fig. 3 and 4).

7. The method according to claim 6 wherein said ratio of a degraded material

property to initial material property includes a ratio of a degraded modulus to an initial modulus (Fig. 3 and 4).

8. The method according to claim 6 wherein said ratio of a degraded material property to initial material property includes a ratio of a degraded strength to an initial strength(Fig. 3 and 4).

9. The method according to claim 6 wherein said ratio of a degraded material property to initial material property includes a ratio of a degraded thermal conductivity to an initial thermal conductivity (Fig. 3 and 4).

10. The method according to claim 6 wherein said ratio of a degraded material property to initial material property includes a ratio of a degraded electrical conductivity to an initial electrical conductivity (Fig. 3 and 4).

11. The method according to claim 1, further comprising: superposing said material density distribution at predetermined time points using both time, degraded base stiffness, and said weighting factor (Page 438, Table 1 and 2).

12. The method according to claim 1, further comprising: superposing said material density distribution at predetermined time points using density at a global anatomic level (Fig. 5).

13. The method according to claim 12, further comprising: superposing said material density distribution at predetermined time points using density at a physical size smaller than said global anatomic level (Fig. 5)l.

14. The method according to claim 1 wherein said weighting said material density distribution using a weighting factor to determine a weighted density further includes employing material degradation kinetics to enhance said material density distribution (Fig. 5 and 6).

15. The method according to claim 14 wherein said employing material degradation kinetics further comprises employing one chosen from the group consisting essentially of polylactic acid, polyglycolic acid, polyanhdyride, polycaprolactone, tri-calcium phosphate, and hydrogels (Page 440, par. 2).

16. A method of manufacturing a biodegradable/bioresorbable tissue augmentation/reconstruction device, said method comprising: dividing the device into elements having a predicted material density between 0 and 1 (Fig. 1); weighting each predicted material density by a predetermined degradation profile to define a weighted material density (Page 434), said degradation profile being unique to a material used; and calculating a material weight in each of said element by applying a time lasting factor and a degrading modulus factor such that high load bearing regions within said device are reinforced to compensate for subsequent stiffness degradation due to bulk erosion of said device (Equation

1 and 2, page 434-435).

17. The method according to claim 16, further comprising: converting said weighted material density to surface representation for manufacture (Fig. 5-6).

18. The method according to claim 17 wherein said converting said weighted material density to surface representation for manufacture includes converting said weighted material density to a STL surface representation (Fig. 5-6).

19. The method according to claim 17 wherein said converting said weighted material density to surface representation for manufacture includes converting said weighted material density to a Computer Aided Design (CAD) surface (Fig. 2).

20. The method according to claim 17 wherein said converting said weighted material density to surface representation for manufacture includes converting said weighted material density to a wireframe representation (Fig. 5-6).

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed Kidest Bahta whose telephone number is 571-

272-3737. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached on 571-272-3753. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval IPAIRI system. Status information for published applications may be obtained from either Private PMR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAG system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-fee).

/Kidest Bahta/

Primary Examiner, Art Unit 2123